PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Sung-Soo PARK	Examiner:	Susan Marie Hanley
Serial No.	10/608,372	Group Art Unit:	1651
Filed:	June 27, 2003	Docket No.	75766.010400
Title:	BIO-ARTIFICIAL LIVER SYSTEM		
Customer No.:	33,717		

CERTIFICATE UNDER 37 CFR 1.6(d)

I hereby certify that this correspondence and identified enclosures are being transmitted via electronic transmission only to Examiner Susan Marie Hanley, Art Unit 1651, Facsimile No. (571) 273-8300 on May 17, 2006.

Victoria King

Name: Victoria King

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT MAILED 4/19/2006

MAIL STOP: AMENDMENT
Hon. Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action mailed April 19, 2006, Applicant respectfully elects Group I, viz. claims 1 – 14 which the Examiner states are *drawn to a bio-artificial liver, classified in class 435, subclass 303.1.* This restriction is done provisionally, and with traverse, in that applicant's system can be used for detoxification of plasma from a mammal and that is the subject matter toward which the instant applications' claims have been directed, as well as the currently pending submission to the U.S. Food and Drug Administration.

The application respectfully points out that the methods taught by the unelected groups may not be practiced without the teachings of the present disclosure. As cited by the Examiner, MPEP § 806.05(h) allows for a restriction between products and processes if (A) the process of using as claimed can be practiced with another materially different product or (B) the product as

claimed can be used in a materially different process. The present disclosure teaches a system that simulates the function of the liver as an organ, rather than as disparate hepatic cells, which is the current technology. Generally, experiments conducted in an *in vitro* system do not always yield the same results as an experiment conducted in *in vivo* systems. The applicant's disclosure essentially teaches a system that allows researchers to get *in vivo* results in an *in vitro* system by creating a fully functioning "artificial" liver on an organ level.

Because the method depends on a system that mimics function at the organ, *in vivo* level rather than the cellular, *in vitro* level, the method is unusable outside of the disclosed system. Nor can the system be used with a materially different process and still maintain the organ level functionality. Thus, the method and system are not simply complements of each other, but rather each is essential to the functionality of the other. For these reasons, the applicant respectfully submits that the restriction requirement was improper and that the restriction requirement should be withdrawn.

While the Examiner points out other usages that she hypothecates the methods of Group II and Group III could be used for, no comment is offered for consideration by applicant at this time as to these representations, as none is seen as salient in order to advance prosecution in this important subject matter, advancing the likelihood of clinical progress and the support of ameliorated and otherwise enhanced patient outcomes using said technology.

The remaining claims are withdrawn, without prejudice and maintaining all divisional rights. Remarks begin on page 6. It is respectfully requested that this case is in a condition for allowance and such relief is hereby earnestly solicited.

A complete listing of the claims follows, and kindly withdraw claims 14 - 18, without prejudice.

AMENDMENTS TO THE CLAIMS

Claim 1 (original): A bioartificial liver system for treating hepatic functional impairment, said system comprising:

a means for separating a blood stream from a patient into plasma and blood cells;

a means for detoxifying the plasma, said means comprising:

a sealable chamber having a plasma inlet and a gas inlet;

a plurality of animal liver slices; and

a mesh at least partially surrounding said animal liver slices so as to form a space and to retain said slices within said space, said mesh being positioned approximately horizontal at or near an upper portion of the chamber;

a means for selectively supplying and removing plasma from the chamber, said means being configured so that when the plasma is supplied to the chamber the plasma comes into contact with the liver slices, and when the plasma is removed from the chamber the plasma is not in contact with the liver slices;

a means for supplying a gas to the top of the chamber;

a reservoir for containing plasma as it enters and exits the chamber; and

a means for reintroducing the plasma and blood cells back to the patient,

wherein said animal liver slices are cultured in an environment of an oxygenated gas and under the supply of a liquid culture medium so that said slices are exposed alternatively at regular intervals to said medium and to said gas thereby detoxifying the plasma and treating hepatic functional impairment.

Claim 2 (original): The system of claim 1, the culture apparatus further comprising a second reservoir for receiving detoxified plasma from the chamber.

Claim 3 (original): The system of claim 1, wherein the gas is a mixture of oxygen and carbon dioxide.

Claim 4 (original): The system of claim 3, wherein the gas-to-plasma exposure time ratio to the animal liver slices is about 1:2 to about 1:4.

Claim 5 (original): The system of claim 3, wherein the gas-to-plasma exposure time ratio to the animal liver slices is about 1:3.

Claim 6 (original): The system of claim 2, further comprising an immunological filter inserted downstream from the second reservoir.

Claim 7 (original): The system of claim 1, wherein the chamber is thermoregulated.

Claim 8 (original): A bioartificial liver system for treating a patient with hepatic functional impairment, said system comprising:

a means for separating a blood stream taken from the patient into a plasma stream and a blood cell stream; and

a liver-slice culture apparatus used as a bioreactor to detoxify the plasma stream, the culture apparatus comprising:

a sealable chamber having a plasma inlet and a gas inlet;

at least two meshes mounted approximately parallel, one above the other, near the upper portion of the chamber so as to form at least two approximately horizontal layers separated by a space;

a plurality of animal liver slices positioned within said space;

means for selectively supplying and removing plasma in the chamber so that the plasma in the chamber comes into contact with the liver slices, and is removed from contact with the liver slices;

means for supplying a gas to the top of the chamber; and

a reservoir for containing plasma as it enters and exits the chamber, said animal liver slices being cultured in an environment of an oxygenated gas under the supply of a liquid culture medium at regular intervals so that said slices are exposed alternatively to the medium and to the gas.

Claim 9 (original): The system of claim 8, the culture apparatus further comprising a second reservoir for receiving detoxified plasma from the chamber.

Claim 10 (original): The system of claim 8, wherein the gas is a mixture of oxygen and carbon

dioxide.

Claim 11 (original): The system of claim 10, wherein the gas-to-plasma exposure time ratio to the animal liver slices is about 1:2 to about 1:4.

Claim 12 (original): The system of claim 10, wherein the gas-to-plasma exposure time ratio to the animal liver slices is about 1:3.

Claim 13 (original): The system of claim 9, further comprising an immunological filter inserted downstream from the second reservoir.

Claim 14 (original): The system of claim 8, wherein the chamber is thermoregulated.

Claim 15 (withdrawn): A method to detoxify the plasma from a mammal, the method comprising:

separating plasma from whole blood of the mammal;

contacting the plasma with animal liver slices, the animal liver slices being contained in a bioreactor, the bioreactor being made up of a sealable chamber having a plasma inlet and a gas inlet, at least two meshes mounted approximately parallel, one above the other near the upper portion of the chamber so as to form at least two approximately horizontal layers separated by a space, a plurality of animal liver slices positioned within said space, means for selectively supplying and removing plasma in the chamber so that the plasma in the chamber comes into contact with the liver slices. and is removed from contact with the liver slices, means for supplying a gas to the top of the chamber, a reservoir for containing plasma as it enters and exits the chamber the space between two meshes, the method further comprising the steps of:

contacting the liver slices with a gas mixture of oxygen and carbon dioxide;

exposing the liver slices alternatively to plasma and the gas mixture of oxygen and carbon dioxide gas; and

returning detoxified plasma to the mammal.

Claim 16 (withdrawn): The method of claim 15, wherein the gas-to-plasma exposure time ratio to the animal liver slices is about 1:3.

Claim 17 (withdrawn): A method of treating a hepatic failure patient, the method comprising:

separating the plasma from the whole blood of the mammal;

contacting the plasma with animal liver slices contained in a space between two meshes;

contacting the liver slices with a gas mixture of oxygen and carbon dioxide;

exposing the liver slices alternatively to the plasma and the gas mixture of oxygen and carbon dioxide gas; and

returning to detoxified plasma to the mammal and the mammal's blood is thereby detoxified.

Claim 18 (withdrawn): The method of claim 17, wherein the gas-to-plasma exposure time ratio to the animal liver slices is about 1:3.

REMARKS

Claims 1 – 13 have been elected, provisionally and with traverse. The remaining claims have been withdrawn, without prejudice. The Examiner is thanked for her attention to this matter.

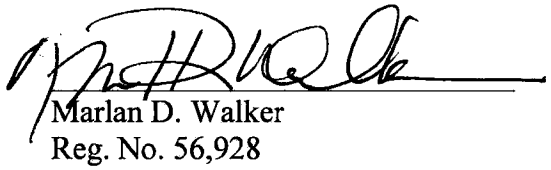
To accommodate the USPTO and to advance prosecution, Group 1 is elected and the remaining claims withdrawn, or hereby cancelled without prejudice.

It is believed that applicant's invention was defined in original and as amended as an integral subject matter and the instant agreement made solely to advance prosecution.

It is respectfully submitted that the application is now in order for allowance. Accordingly, reconsideration of the application and allowance thereof is hereby courteously solicited.

This response is being timely filed and no fee is believed due. However, if Applicants are mistaken, the Commissioner is hereby authorized to charge any required fee in connection with the submission of this paper, now or in the future, or credit any overpayment to Account No. 50-2638. Please ensure that Attorney Docket Number 75766.010400 is referred to when charging any payments or credits for this case.

Respectfully submitted,



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